

**CLAIMS**

What is claimed:

1. A process for preparing a hemostatic device, comprising:
  - (a) suspending a plurality of collagen particles in water to form a collagen slurry, wherein  
5 the collagen particles have a bulk density sufficient to form a suspension in water and wherein  
the collagen slurry has a collagen concentration in the range of about 1% to about 2%  
(weight/volume); and
  - (b) lyophilizing the collagen slurry to form a hemostatic device.
- 10 2. The process of claim 1, wherein the collagen particles comprise collagen fibrils
3. The process of claim 1, wherein the collagen particles have a bulk density in the range of  
about 1.5 lbs/ft<sup>3</sup> to about 3.5 lbs/ft<sup>3</sup>.
- 15 4. The process of claim 1, wherein the process comprises the further step of:  
introducing the collagen slurry into a mold prior to lyophilizing the collagen slurry.
5. The process of claim 1, wherein the process further comprises the step of crosslinking the  
hemostatic device to form a crosslinked-hemostatic device.
- 20 6. The process of claim 1, comprising the further step of introducing a hemostatic agent into  
one or both of the collagen slurry and the hemostatic device.
7. The process of claim 1, comprising the further step of introducing a hemostatic agent into  
25 one or both of the collagen slurry and the hemostatic device.
8. The process of claim 1, comprising the further step of removing a surface layer of the  
hemostatic device.
- 30 9. A hemostatic device prepared by the process comprising:
  - (a) suspending a plurality of collagen particles in water to form a collagen slurry, wherein

the collagen particles have a bulk density sufficient to form a suspension in water and wherein the collagen slurry has a collagen concentration in the range of about 1% to about 2% (weight/volume); and

(b) lyophilizing the collagen slurry to form a hemostatic device.

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10. The product of claim 9, wherein the collagen particles comprise microfibrillar collagen.

11. The product of claim 9, wherein the collagen particles have a bulk density in the range  
10 of about 1.5 lbs/ft<sup>3</sup> to about 3.5 lbs/ft<sup>3</sup>.

12. The product of claim 9, wherein the process comprises the further step of introducing the collagen slurry into a mold prior to lyophilizing the collagen slurry.

15 13. The product of claim 9, wherein the process further comprises the step of crosslinking the hemostatic device to form a crosslinked-hemostatic device.

14. The product of claim 9, wherein the process further comprises the step of removing a surface layer of the hemostatic device.

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15. The product of claim 9, wherein the process further comprises the step introducing into the hemostatic device, a hemostasis-promoting amount of at least one hemostatic agent effective to accelerate clot formation at an interface between a wound surface and the hemostatic device.

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16. The product of claim 9, wherein the process further comprises the step introducing into the hemostatic device, a therapeutically-effective amount of at least one therapeutic agent.

17. A sterile package containing the hemostatic device of claim 9.

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18. A method for promoting hemostasis comprising, manually pressing the hemostatic

device of claim 9 against a bleeding surface for a period of time until clotting has occurred at the interface between the hemostatic device and the surface.

19. A hemostatic device, wherein the collagen particles of the hemostatic device have a hemostatic activity that is equivalent to the hemostatic activity of the collagen particles from which the hemostatic device is formed.

20. The hemostatic device of claim 19, wherein the hemostatic device is a foam.

21. The hemostatic device of claim 19, wherein the hemostatic device does not contain thrombin and the hemostatic device has a hemostatic activity in a pig spleen animal model that is greater than that of Gelfoam ® with thrombin.

22. The hemostatic device of claim 19, wherein the hemostatic device has a thickness of about 3/8 inch and an acute maximum load of greater than or equal to 0.08 lbs.

23. The hemostatic device of claim 19, wherein the hemostatic device is dry and has a modulus of less than or equal to 86 psi.

24. The hemostatic device of claim 19, wherein the hemostatic device has a wettability index of less than or equal to 1 minute in distilled water at room temperature.

25. The hemostatic device of claim 19, further comprising a hemostasis-promoting amount of at least one hemostatic agent effective to accelerate clot formation at an interface between a wound surface and the hemostatic device.

26. The hemostatic device of claim 19, further comprising a therapeutically-effective amount of at least one therapeutic agent.

27. The hemostatic device of claim 19, further comprising a hemostasis-promoting amount of at least one hemostatic agent effective to accelerate clot formation at an interface between a

wound surface and the hemostatic device.

28. A sterile package containing a hemostatic device of claim 19.

5 29. A method for promoting hemostasis comprising, manually pressing a hemostatic device of claim 19 against a bleeding surface for a period of time until clotting has occurred at the interface between the hemostatic device and the surface.

30. A hemostatic device comprising collagen, wherein the hemostatic device has a  
10 hemostatic activity in a pig spleen animal model of hemostasis that corresponds to one tamponade for a hemostatic device having a thickness of  $\frac{3}{8}$  inch, a length of  $\frac{1}{2}$  inch, and a width of  $\frac{1}{2}$  inch.

31. The hemostatic device of claim 30, wherein the hemostatic device does not contain  
15 thrombin and the hemostatic device has a hemostatic activity in a pig spleen animal model that is greater than that of Gelfoam ® with thrombin.

32. The hemostatic device of claim 30, wherein the hemostatic device has a density in the  
range of about 0.015 to about 0.023 gm/cc.

20 33. The hemostatic device of claim 30, wherein the hemostatic device has a weight percent solids in the range of about 1.10 to about 1.64 weight percent.

34. The hemostatic device of claim 30, wherein the hemostatic device has a thickness of  
25 about  $\frac{3}{8}$  inch and an acute maximum load of greater than or equal to 0.08 lbs.

35. The hemostatic device of claim 30, wherein the hemostatic device is dry and has a modulus of less than or equal to 86 psi.

30 36. The hemostatic device of claim 30, wherein the hemostatic device has a wettability index of less than or equal to 1 minute in distilled water at room temperature.

37. The hemostatic device of claim 30, further comprising a hemostasis-promoting amount of at least one hemostatic agent effective to accelerate clot formation at an interface between a wound surface and the hemostatic device.

5 38. The hemostatic device of claim 30, further comprising a therapeutically-effective amount of at least one therapeutic agent.

39. A hemostatic device comprising collagen, wherein the hemostatic device is dry and sufficiently flexible to conform to the contours of a biological surface and absorb exudants  
10 present at the biological surface.